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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/618,835
				Filing Date	07/15/2003
Date Submitted: April 9, 2004				First Named Inventor	John P. Cooke
				Group Art Unit	1654
(use as many sheets as necessary)				Examiner Name	J. Russel
				Attorney Docket Number	080618-0237
Sheet	1	of	1		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
JR	D1	5,372,807		POIANI et al.	12-13-1994	424/78,36
JR	D2	5,278,189		RATH et al.	01-11-1994	514/561

FOREIGN PATENT DOCUMENTS						
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		Office ³	Number ⁴	Kind Code ⁵ (if known)		
JR	D3		WO 88/01872		03-24-1988	
JR	D4		EP 0 483 614 A		05-06-1992	
JR	D5		WO 94/16729 A		08-04-1994	
JR	D6		GB 953,997		04-02-1964	
JR	D7		EP 0 546 796 A1		06-16-1993	
JR	D8		WO 94/28721 A		12-22-1994	
JR	D9		GB 1,304,499		01-24-1973	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		
JR	D10	RIBEIRO, ALDA, et al., "Arginine-Lysine Combination in Immunodepressed Elderly Patients, Long-Term Controlled Trial," <i>Clinical Trials Journal</i> 1986, United Kingdom, vol. 23, no. 3, pp. 185-192.		
JR	D11	IGNARRO, LOUIS J., et al., "Basic Polyamino Acids Rich in Arginine, Lysine, or Ornithine Cause Both Enhancement of and Refractoriness to Formation of Endothelium-Derived Nitric Oxide in Pulmonary Artery and Vein," <i>Circulation Research</i> , vol. 64, no. 2, 1989, pages 315-329.		

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Examiner Signature	Jeffrey E. Russe	Date Considered	September 8, 2004
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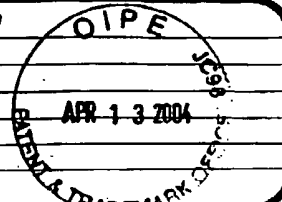
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JR	E1	COOKE, JOHN P., et al., "Antiatherogenic Effects of L-Arginine in the Hypercholesterolemic Rabbit," <i>Journal of Clinical Investigation</i> , vol. 90, September 1992, pp. 1168-1172.	
JR	E2	MARIN, JESUS, et al., "Role of Endothelium-Formed Nitric Oxide on Vascular Responses," <i>General Pharmacology</i> , vol. 21, no. 5, 1990, pp. 575-587.	
JR	E3	JANSSENS, STEFAN P., et al., "Cloning and Expression of a cDNA Encoding Human Endothelium-derived Relaxing Factor/Nitric Oxide Synthase," <i>Journal of Biological Chemistry</i> , vol. 267, no. 21, July 25, 1992, pp. 14519-14522.	

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Attorney Docket Number	080618-0237

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JR	A1	2,878,124		KRUKENBERG	03-17-1959	514/557
JR	A2	3,015,567		HAUSE et al.	01-02-1962	426/650
JR	A3	3,360,374		BARR, SR. et al.	12-26-1967	426/615
JR	A4	3,970,750		BROCKEMEYER et al.	07-20-1976	424/679
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JR	A6	4,340,592		ADIBI	07-20-1982	514/118
JR	A7	4,900,566		HOWARD	02-13-1990	426/72
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JR	A9	4,957,938		ANDERSON et al.	09-18-1990	514/412
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JR	A12	5,034,377		ADIBI et al.	07-23-1991	514/118
JR	A13	5,036,052		OZEKI et al.	07-30-1991	514/19
JR	A14	5,041,429		SAWAI et al.	08-20-1991	514/143
JR	A15	5,106,836		CLEMENS et al.	04-21-1992	514/81
JR	A16	5,157,022		BARBUL	10-20-1992	514/18
JR	A17	5,171,217		MARCH et al.	12-15-1992	604/53
JR	A18	5,217,997		LEVERE et al.	06-08-1993	514/565
JR	A19	5,221,668		HENNINGFIELD et al.	06-22-1993	514/23
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JR	A21	5,262,435		JOSHUA et al.	11-16-1993	514/452
JR	A22	5,278,189		RATH et al.	01-11-1994	514/561
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JR	A26	5,334,617		ULRICH et al.	08-02-1994	514/562
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JR	A28	5,374,651		KILBOURN et al.	12-20-1994	514/400
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JR	A33	5,543,430		KAESEMEYER et al.	08-06-1996	514/565
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JR	A36	5,626,883		PAUL	05-06-1997	424/605
JR	A37	5,631,031		MEADE	05-20-1997	426/2
JR	A38	5,650,418		RATH et al.	07-22-1997	514/356
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JR	A41	5,830,848		HARRISON et al.	11-03-1998	514/2
JR	A42	5,891,459		COOKE et al.	04-06-1999	424 / 439
JR	A43	5,965,529		GARFIELD et al.	10-12-1999	514/12

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 Examiner
Signature

Jeffrey E. Russel

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U.S. PATENT DOCUMENTS						Class/Subclass
		U.S. Patent Document				
JR	A44	5,945,452		COOKE et al.	08-31-1999	514 / 564
JR	A45	6,063,432		MAXWELL et al.	05-16-2000	426 / 656
JR	A46	6,083,515		GARVEY et al.	07-04-2000	424 / 400
JR	A47	5,348,755		ROY	09-20-1994	426 / 541
JR	B1	5,229,390		MORIYAMA et al.	07-20-1993	514 / 263, 32
JR	B2	5,352,695		N'GUYEN et al.	10-04-1994	514 / 423

FOREIGN PATENT DOCUMENTS								Class/Subclass
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
JR	A48	JP	50-48189			04-30-1975		
JR	A49	JP	57-5692			01-12-1982		
JR	A50	JP	57-93913			06-11-1982		
JR	A51	JP	58-55418			04-01-1983		
JR	A52	EP	0441119A2		LEVERE et al.	08-14-1991		
JR	A53	JP	3-21786			01-30-1991		
JR	A54	EP	0511587		MORIYAMA	11-04-1992		
JR	A55	EP	0511118A1		L'OREAL	10-28-1992		
JR	A56	EP	0546796A1		SONAKA	06-16-1992		
JR	A57	ZA	93-6619		DAVIS et al.	09-15-1993		
JR	A58	WO	93-18156		BLOCH et al.	09-16-1993		
JR	A59	JP	7-163269			06-27-1995		
JR	A60	FR	2,547,501		DONZEAU	12-1984		

OTHER - NON PATENT LITERATURE DOCUMENTS					T ²
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JR	A61	MERIMEE et al.; "Arginine infusion in maturity-onset diabetes mellitus"; <i>The Lancet</i> (June 11, 1966), pp. 1300-01.			
JR	A62	DI ROSA; "Azione anti-ammoniemicca ed epatoprotettiva di una associazione a base di pirrolidonecarbossilato di arginina, taurina e vitamina B ₆ "; <i>Lavoro ricevuto</i> (July 14, 1967).			
JR	A63	RASK et al.; "Studies on two physiological forms of the human retinol-binding protein differing in Vitamin A and Arginine content"; <i>The Journal of Biological Chemistry</i> , Vol. 246, No. 21 (November 10, 1971), pp. 6638-46.			
JR	A64	KADIRVEL et al.; "Uptake of L-Arginine and L-Lysine by the small intestine and its influence on Arginine-Lysine antagonism in chicks"; <i>Journal of Nutrition</i> , Vol. 103, No. 3 (March, 1974), pp. 339-43.			

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Examiner Signature	Jeffrey E. Russel	Date Considered	September 7, 2004
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JR	A65	BARNES et al.; "The effect of calcium ions on the hydrolysis of benzolarginine ethyl ester by porcine enteropeptidase"; <i>Biochemica et Biophysica Acta</i> ; 452 (1976), pp. 161-64.	
JR	A66	LECLERCQ-MEYER et al.; "The Role of Calcium in Glucagon Release"; <i>Hormone Res.</i> 7:348-362 (1976).	
JR	A67	CAMPILLO et al.; "Effect of various concentrations of calcium on Arginine-induced insulin and Glucagon release in vitro"; <i>Revista Espanola de Fisiologica</i> , Vol. 34 (1978), pp. 191-98.	
JR	A68	BORNHOF et al.; "Hemodynamic splanchnic and renal changes associated with administration of arginine-hydrochloride in dogs"; <i>Res. Exp. Med.</i> (1980) 177:57-70.	
JR	A69	KECK et al.; "Beeinflussung des Arginininfusions- und Insulin-Toleranz-Tests durch erhöhtes Serumcalcium"; <i>akt. Endokrin.</i> 1:135-142 (1980).	
JR	A70	FURCHGOTT et al.; "The Obligatory role of endothelial cells in the relaxation of arterial smooth muscle by acetylcholine"; <i>Nature</i> (11-27-1980), pp. 373-76.	
JR	A71	CALVER et al.; "Dilator actions of arginine in human peripheral vasculature"; <i>Clinical Science</i> (1981) 81:695-700.	
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JR	A74	KATAN et al.; "Reduction of Casein-induced Hypercholesterolaemia and Atherosclerosis in Rabbits and Rats by Dietary Glycine, Arginine an Alanine"; <i>Elsevier Nothe Holland Scientific Publishers, Ltd.</i> (1982), Atherosclerosis 43:381-91.	
JR	A75	PEARSON et al.; "Chapter 5: Aging and the Immune System"; <i>Life Extension</i> (1982).	
JR	A76	BECKEL et al.; "Antioxidative Arginine-Xylose Maillard Reaction Products: Conditions for Synthesis"; <i>Journal of Food Science</i> , Vol. 48 (1983), pp. 996-97.	
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JR	A79	WOOD et al.; "Evidence for Insulin Involvement in Arginine- and Glucose-Induced Hypercalciuria in the Rat"; <i>The Journal of Nutrition</i> , Vol. 113, No. 8 (1983), pp. 1561-67.	
JR	A80	TANAKA et al.; "Calcium-dependent interactions with calmodulin of a florescent calmodulin antagonist: N ² -dansyl-L-arginine-4-t-butylpiperidine amide"; <i>Archives of Biochemistry and Biophysics</i> , Vol. 220, No. 1 (01-83), pp. 188-92.	
JR	A81	OLSON et al.; "Avian shell gland contractility: interaction of PGF _{2α} and arginine vasotocin with Ca ²⁺ "; <i>American Journal of Physiology</i> Vol. 244, No. 3 (03-83), pp. C150-57.	

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JR	A82	HERCHUELZ et al.; "Mechanism of arginine-stimulated Ca ²⁺ influx into pancreatic B cell"; <i>American Journal of Physiology</i> , Vol. 246, No. 1 (01-84), pp. E38-43.	
JR	A83	DAVRIL et al.; "Arginine Modification in Elastase"; <i>Journal of Biological Chemistry</i> , Vol. 259, No. 6 (03-25-1984), pp. 3851-57	
JR	A84	BARBUL et al.; "High Arginine levels in Intravenous Hyperalimentation Abrogate Post-Traumatic Immune Suppression"; <i>Journal of Surgical Research</i> (06-1984) 36:620-24.	
JR	A85	HEISTAD et al.; "Augmented responses to vasoconstrictor stimuli in hypercholesterolemic and atherosclerotic monkeys"; <i>Circulation Research</i> , Vol. 54, No. 6 (06-84), pp. 711-18.	
JR	A86	PALMER et al.; "Vascular endothelial cells synthesize nitric oxide from L-Arginine"; <i>Nature</i> (06-16-1984) 333:664-66.	
JR	A87	BARBUL et al.; "Intravenous Hyperalimentation with High Arginine Levels Improves Wound Healing and Immune Function"; <i>Journal of Surgical Research</i> (04-1985) 638:328-34.	
JR	A88	HOSANG; "Suramin Binds to Platelet-Derived Growth Factor and Inhibits Its Biological Activity"; <i>Journal of Cellular Chemistry</i> (04-30-1985) 29:265-73.	
JR	A89	WATANABE et al.; "Effects of Vitamin E and Arginine on the Metabolism of Alcohol"; <i>Nutrition Reports International</i> , Vol. 32, No. 1 (07-85), pp. 149-53	
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		First Named Inventor	John P. Cooke
		Group Art Unit	1654
		Examiner Name	J. Russel
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		Attorney Docket Number	080618-0237

OTHER - NON PATENT LITERATURE DOCUMENTS

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JR	A99	HENRIKSON et al.; "Separation and Identification of Two Components of an Estrogen-Responsive, Calcium-Dependent Arginine Esteropeptidase"; <i>J. Steroid Biochem</i> , Vol. 24, No. 2; pp. 189-196 (1987).	
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Date Submitted: April 19, 2004

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JR	A115	ALBINA et al.; "Regulation of Macrophage Functions by L-Arginine"; <i>J. Exp. Med</i> (03-1989) 169:1021-29.	
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JR	A147	MILYUTINA et al.; "Antiradical and Antioxidative Effect of Arginine and Its Influence on Lipid Peroxidation Activity During Hypoxia"; Bull. Exp. Biol. And Medicine (1991), 110(9):1198-1200.	
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JR	A179	JANSSENS et al.; "Cloning and Expression of a cDNA Encoding Human Endothelium-derived Relaxing Factor-Nitric Oxide Synthase"; <i>The Journal of Biological Chemistry</i> , Vol. 267, No. 21 (07-25-92), pp. 14519-22.	

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Examiner Signature	Jeffrey E. Russel	Date Considered	September 7, 2004
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 STATEMENT BY APPLICANT**

Date Submitted: April 19, 2004

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Complete if Known

Application Number	10/618,835
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First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 10 of 13

OTHER - NON PATENT LITERATURE DOCUMENTS

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		Filing Date	07/15/2003
		First Named Inventor	John P. Cooke
		Group Art Unit	1654
		Examiner Name	J. Russel
Date Submitted: April 19, 2004 (use as many sheets as necessary)		Attorney Docket Number	080618-0237
Sheet	11	of	13

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JR	A195	McNAMARA et al.; "L-Arginine Inhibits Balloon Catheter-Induced Intimal Hyperplasia"; <i>Biochemical and Biophysical Research Communications</i> ; Vol. 193, No. 1 (05-28-93), pp. 291-96.	
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First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
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Sheet 12 of 13

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JR	A213	KEYSARY et al.; "The involvement of L-Arginine-Nitric Oxide Pathway in the Anti-Rickettsial Activity of Macrophagelike cells"; <i>Biochemical, Pharmacological, and clinical aspects of Nitric Oxide</i> (1995), pp. 111-14.	
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JR	A228	D. PEARSON and S. SHAW, <u>The Life Extension Companion</u> , Warner Books (1984), NY, pp. cover to cover (1325 pages total).	
JR	A229	D. PEARSON and S. SHAW, <u>The Life Extension Companion</u> , Warner Books (1984), NY, pp. 461-62; 467-68; 485; 611-13; and 620.	
JR	A230	Derwent Abstract of JP 50048189 A, 04/30/1975, "Fermentative production of L-arginine - in presence of antibiotics, surfactants and antioxidants," 1 page.	
JR	A231	Derwent Abstract of JP 57005692 A, 01/12/1982, "Fermentative production of L-arginine - by incubation of microorganism of genus Brevibacterium or Corynebacterium," 1 page.	
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JR	F1	4,900,566		Howard	2/13/1990	426/72
JR	F2	5,106,836		Clemens et al.	4/21/1992	514/21

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JR	F3	EP	0511587	A1	Takeda Chemical Industries, Ltd.	11/04/1992		

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JR	F4	JP60094075A, AJINOMOTO KK; Dialog Japanese Abstract (1 pg.) (May 27, 1985)	
JR	F5	JP61254162A, KAMEHIKO MOGI, Dialog Japanese Abstract (1 pg.) (Nov. 11, 1986)	
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JR	F9	European Search Report dated 7/31/03 for EP Application No. 107776.2	

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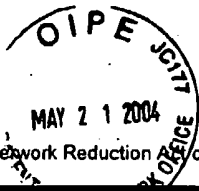
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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: May 21, 2004

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Complete if Known

Application Number	10/618,835
Filing Date	07/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 1 of 15

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
JR	C1	2002/0091160	A1	COOKE, et al.	02-01-2002	574/564
JR	C2	5,026,721		DUDRICK, et al.	06-25-1991	
JR	C3	5,028,627		KILBOURN, et al.	07-02-1991	
JR	C4	6,117,872		MAXWELL, et al.	09-12-2000	
JR	C5	6,337,321		COOKE, et al.	01-08-2002	
JR	C6	6,552,074		KIMOTO, et al.	04-22-2003	
JR	C7	6,646,006		COOKE, et al.	11-11-2003	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
JR	C8	EP	0 259 167 A2		Millman	03-09-1988		
JR	C9	EP	0 511 118 A1		N'Guyen	10-28-1992		
JR	C10	EP	511 587 A1		Moriyama et al.	11-04-1992		
JR	C11	EP	0 546 796 A1		Sonaka et al.	06-16-1993		
JR	C12	WO	98/18491		Burgstiner	05-07-1998		
JR	C13	ZA	9410015 A		Davis et al.	11-08-1995		
JR	C14	FR	2 507 892		Brugioni et al.	12-24-1982		
JR	C14a	GB	2 100 982		Brugioni et al.	06-22-1982		
JR	C15	WO	85/00517		Niebes et al.	02-14-1985		

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JR	C16	Adams et al., "Oral L-arginine improves endothelium-dependent dilatation and reduces monocyte adhesion to endothelial cells in young men with coronary artery disease" <i>Atherosclerosis</i> , 1997, 129(2):261-69.	
JR	C17	Adams et al., "Cigarette smoking is associated with increased human monocyte adhesion to endothelial cells: reversibility with oral L-arginine but not vitamin C," <i>J. Amer. Coll. Cardiol.</i> , 1997, 29(3):491-97.	

Examiner Signature Jeffrey E. Russel

Date Considered

September 7, 2004

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Sheet	2	of	15
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JR	C18	Aimasheva et al., "Donor of nitric oxide improves, while NO-synthase inhibitor impairs resistance and adaptation to strenuous physical exercise," <i>Bulletin of Exp. Biol. and Med.</i> , 1998, 4:336-339.	
JR	C19	Aisaka et al., "N ^G -monomethyl-L-arginine, an inhibitor of endothelium-derived nitric oxide synthesis, abbreviates acetylcholine-induced vasodilatation in the guinea-pig" in <i>Nitric Oxide from L-arginine: a Bioregulatory System</i> (S. Moncada and E.A. Higgs, eds.), 1990, Chapter 40, pp. 379-384.	
JR	C20	Aisaka et al., "Modulation of cardiovascular function by L-arginine-derived nitric oxide" <i>Frontiers and new horizons in amino acid research</i> (K. Takai, ed.), 1992, 437-442.	
JR	C21	Aisaka et al., "Regulation of vascular resistance by L-arginine-derived nitric oxide," <i>J. Pharmacobio-Dyn.</i> , 1992, 15:s-60.	
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JR	C25	Barbul et al., "Arginine" in <i>Nutrition in Critical Care</i> (Gary Zaloga ed.), 1994, Chapter 6, pp. 107-21.	
JR	C26	Barbul A., "Physiology and pharmacology of arginine" in <i>Nitric Oxide from L-Arginine: A Bioregulation System</i> (Moncada, S. and Riggs, E.A., eds.), 1990, Chapter 33, pp. 3 17-29.	
JR	C27	Barbul A., "Arginine and immune function," 1999 ¹⁹⁹⁰ <i>Nutr.</i> 6(1):53-62.	
JR	C28	Barbul et al., "Arginine: a thymotropic and wound-healing promoting agent," 1977, <i>Surg. Forum.</i> 28:101-103.	
JR	C29	Barclay et al., "The role of blood flow in limiting maximal metabolic rate in muscle," 1975, <i>Med Sci Sports.</i> 7(2):116-119.	
JR	C30	Baumier et al., "Arginine: new and exciting developments for an 'old' amino acid," 1996, <i>Biomed. Environ. Sci.</i> 9(2-3):296-315.	
JR	C31	Bellamy et al., "Oral L-arginine improves exercise tolerance and flow-related endothelial dysfunction in microvascular angina," 1996, Abstract No. 2478, <i>Suppl. Circulation</i> 94(8):I-425.	

**Examiner
Signature**

Jeffrey E. Russel

**Date
Considered**

September 7, 2004

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Date Submitted: May 21, 2004

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Complete if Known

Application Number	10/618,835
Filing Date	07/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 3 of 15

NON PATENT LITERATURE DOCUMENTS

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JR	C32	Bissell, "Porphyria," Textbook of Medicine (ed. Wyngaarden and Smith), W.B. Saunders Co., Harcourt Brace Jovanovich Inc. Philadelphia, 1988, pp. 1182-89.	
JR	C33	Blomqvist, "Cardiovascular adaptations to physical training," 1983, Annu. Rev. Physiol. 45:169-89.	
JR	C34	Blum et al., "Oral L-arginine in patients with coronary artery disease on medical management," 2000, Circulation 101:2160-64.	
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JR	C38	Böger et al., "Dietary L-arginine reduces the progression of atherosclerosis in cholesterol-fed rabbits: comparison with lovastatin," 1997, Circulation 96(4):1282-90.	
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JR	C42	Castillo et al., "Plasma arginine, citrulline, and ornithine kinetics in adults, with observations on nitric oxide synthesis" Am. J. Physiol. 1995, 268: E360-E367.	
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JR	C44	Castillo et al., "Endothelium-dependent vasodilatation in rat aorta is mainly mediated by nitric oxide" Proc. West. Pharmacol. Soc. 1997, 40:39-40.	

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Signature

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JR	C45	Castillo et al., "Dietary arginine uptake by the splanchnic region in adult humans" Am J Physiol. 1993, 65(4 Pt 1):E532-39.	
JR	C46	Castillo et al., "Splanchnic metabolism of dietary arginine in relation to nitric oxide synthesis in normal adult man" Proc. Natl. Acad. Sci. USA 1993, 90(1):193-97.	
JR	C47	Castillo et al., "Plasma arginine and citrulline kinetics in adults given adequate and arginine-free diets" Proc. Natl. Acad. Sci. USA 1993, 90:7749-53.	
JR	C48	Castillo et al., "Plasma arginine kinetics in adult man: response to an arginine-free diet" Metabolism 1994, 43(1):114-22.	
JR	C49	Ceremuzkynski et al., "L-arginine improves exercise capacity in patients with stable angina" Supplement to J. of Am. College of Cardiology, 1997, 29(2): Supp. A. Abstract 962-94.	
JR	C50	Ceremuzynski et al., "Effect of supplemental oral L-arginine on exercise capacity in patients with stable angina pectoris" Am. J. Cardiol. 1997, 80(3):331-33.	
JR	C51	Chauhan et al., "Aging-associated endothelial dysfunction in humans is reversed by L-arginine" J. Amer. Coll Cardiol. 1996, 28(7):1796-1804.	
JR	C52	Chen et al., "L-arginine prevents hypertension in salt-sensitive (SS/Jr) Dahl/Rapp rats" Clinical Research 1991, 39:379A.	
JR	C53	Chen et al., "Hypertensive Nephrosclerosis in the Dahl/Rapp Rat: Initial Sites of Injury and Effect of Dietary L-Arginine Supplementation" Laboratory Investigation 1993, 68(2):174-184.	
JR	C54	Chen et al., "Effects of chronic treatment with L-arginine on atherosclerosis in ApoE knockout and ApoE/inducible NO synthase double-knockout mice" Arterioscler. Thromb. Vasc. Biol. 2003, 23:97-103.	
JR	C55	Cheng et al., "L-arginine in the management of cardiovascular diseases" Ann Pharmacother, 2001, 35(6):755-64.	
JR	C56	Chester et al., "Low basal and stimulated release of nitric oxide in atherosclerotic epicardial coronary arteries" Lancet 1990, 336(8720):897-900.	
JR	C57	Chester et al., "The role of nitric oxide in mediating endothelium dependent relaxations in the human epicardial coronary artery" Int J Cardiol. 1990, 29(3):305-09.	

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<i>JR</i>	C58	Church et al., "Hypertension and renal impairment as complications of acute porphyria" Nephrol Dial Transplant. 1992, 7(10):986-90.	
<i>JR</i>	C59	Cooke et al., "Endothelial dysfunction in hypercholesterolemia is corrected by L-arginine" Basic Res Cardiol., 1991, 86 Suppl 2:173-81.	
<i>JR</i>	C60	Cooke J.P., "A peculiar result and a fanciful hypothesis regarding L-arginine" Atheroscler. Thromb. Vasc. Biol. 2003, 23:1128-31.	
<i>JR</i>	C61	Creager et al., "L-arginine improves endothelium-dependent vasodilation in hypercholesterolemic humans" Supplement to Circulation 1990, 82:III-346, 1248-1253.	
<i>JR</i>	C62	Cynober et al., "Arginine metabolism in mammals" J. Nutr. Biochem. 1995, 6:402-13.	
<i>JR</i>	C63	Davies et al., "Combination therapy of cholesterol reduction and L-arginine supplementation controls accelerated vein graft atheroma" Ann. Vasc. Surg. 1999, 13(5):484-93.	
<i>JR</i>	C64	de Graaf JC et al., "Nitric oxide functions as an inhibitor of platelet adhesion under flow conditions". Circulation 1992, (6):2284-90.	
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<i>JR</i>	C67	Dubois-Rande, Jean-Luc et al., "L-arginine improves endothelium-dependent relaxation of conductance and resistance coronary arteries in coronary artery disease" J. of Cardio Pharm. 1992, 20(Suppl. 12):S211-S213.	
<i>JR</i>	C68	Edmonds et al., "Urea cycle metabolism: effects of supplemental ornithine or citrulline on performance, tissue amino acid concentrations and enzymatic activity in young pigs fed arginine-deficient diets" Anim. Sci. 1987, 65(3):706-16.	
<i>JR</i>	C69	Eklund et al., "Effects of the Source of Dietary Protein on Serum Lower Density Lipoprotein (VLDL + LDL) and Serum Tocopherol Levels in Female Rats" J. Nutr. 1980, 110(12):2321-35.	
<i>JR</i>	C70	Elder et al., "The acute porphyrias" Lancet. 1997 349(9065):1613-17.	
<i>JR</i>	C71	Elder et al., "Treatment of acute porphyria" Hosp Med. 2001, 62(7):422-25.	

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Jn	C72	Feng Q., et al., "Endothelium-derived relaxing factor (EDRF) and nitric oxide (NO). I. Physiology, pharmacology and pathophysiological implications" Clin. Physiol. 1990, (5):407-26.	
Jn	C73	Freiman et al., "Atherosclerosis impairs endothelium-dependent vascular relaxation to acetylcholine and thrombin in primates," Circ Res. 1986, 58(6):783-89.	
Jn	C74	Frick et al., "Cardiovascular dimensions and moderate physical training in young men" J Appl. Physiol. 1970, 29(4):452-55.	
Jn	C75	Furchgott et al., "Interactions of endothelial cells and smooth muscle cells of arteries" Chest. 1985, 88(4 Suppl):210S-213S.	
Jn	C76	Martin et al., "Depression of contractile responses in rat aorta by spontaneously released endothelium-derived relaxing factor" Pharmacol. Exp. Ther. 1986, 237(2):529-38.	
Jn	C77	Furchgott et al., "Evidence for endothelium-dependent vasodilation of resistance vessels by acetylcholine" Blood Vessels. 1987, 24(3):145-49.	
Jn	C78	Furchgott et al., "Evidence supporting the proposal that endothelium-derived relaxing factor is nitric oxide" Thrombosis Research 1987, Supp. VII:5.	
Jn	C79	Furchgott et al., "Evidence that the endothelium-derived relaxing factor of rabbit aorta is nitric oxide" Dept. of Pharmacology, SUNY Health Science Center at Brooklyn, NY, 1988, 77-84.	
Jn	C80	Furchgott et al., "Endothelium-derived relaxing and contracting factors" FASEB J. 1989, 3(9):2007-18.	
Jn	C81	Furchgott et al., "Interactions of superoxide and hydrogen peroxide with nitric oxide and EDRF in the regulation of vascular tone" Endothelium-Derived Factors and Vascular Functions (T. Masaki, ed.), 1994, pp. 3-11.	
Jn	C82	Furchgott RF et al., "Endothelial cells as mediators of vasodilation of arteries" J Cardiovasc Pharmacol. 6 Suppl 1984, 2:S336-43.	
Jn	C83	Furchgott RF, "The pharmacology of vascular smooth muscle" Pharmacol Rev. 1955, 7(2):183-265.	
Jn	C84	Furchgott RF, "A research trail over half a century" Ann. Rev. Pharmacol. Toxicol. 1995, 35:1-27.	
Jn	C85	Furchgott RE, Bhadrakom S, "Reactions of strips of rabbit aorta to epinephrine, isopropylarterenol, sodium nitrite and other drugs" J. Pharmacol. Exp. Ther. 1953, 108(2):129-43.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: May 21, 2004 (use as many sheets as necessary)		Application Number	10/618,835
		Filing Date	07/15/2003
		First Named Inventor	John P. Cooke
		Group Art Unit	1654
		Examiner Name	J. Russel
Sheet	7	of	15
		Attorney Docket Number	080618-0237

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
JR	C86	Furchgott, RF, "The role of endothelium in the responses of vascular smooth muscle to drugs" Ann. Rev. Pharmacol. Toxicol. 1984, 24:175-97.	
JR	C87	Furchgott, RF, "The 1989 Ulf von Euler lecture. Studies on endothelium-dependent vasodilation and the endothelium-derived relaxing factor" Acta Physiol. Scand. 1990, 139(2):257-70.	
JR	C88	Furchgott, RF, "Introduction to EDRF Research" J. Cardiovascular Pharmacology Vol. 22, Supplement 7, 1993, pp. S1-S2.	
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JR	C90	Furchgott, RF, "The Discovery of Endothelium-Derived Relaxing Factor and Its Importance in the Identification of Nitric Oxide" JAMA 1996, 276(14) 1186-88.	
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JR	C92	Furchgott, RF, "Endothelium-derived relaxing factor: discovery, early studies, and identification as nitric oxide" Biosci. Rep. 1999, 19(4):235-51.	
JR	C93	Ghigo et al., "Low doses of either intravenously or orally administered arginine are able to enhance growth hormone response to growth hormone releasing hormone in elderly subjects" J. Endocrinol Invest. 1994, 17(2): 113-22.	
JR	C94	Gordon, "The acute porphyrias" Brain Dev. 1999, 21(6):373-77.	
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Examiner Signature	Jeffrey E. Russel	Date Considered	September 7, 2004
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First Named Inventor	John P. Cooke
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Sheet 8 of 15

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JR	C99	Henderson, (St Cyres lecture) "Endothelium in control," Br. Heart J. 1991, 65(3):116-25.	
JR	C100	Hishikawa et al., "L-arginine-induced hypertension" Lancet 1991, 337:683-84.	
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JR	C108	Kauppinen, "Management of the acute porphyrias" Photodermatol. Photoimmunol. Photomed. 1988, 14(2):48-51.	
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JR	C112	Kordac, et al., "Changes of myocardial functions in acute hepatic porphyrias. Role of heme arginate administration," Annals of Medicine 1989, 21(4):273-76.	

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		Attorney Docket Number	080618-0237

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JR	C113	Lais, et al., "Mechanism of vascular hyperresponsiveness in the spontaneously hypertensive rat," Circ Res. 1975, 36(6 Suppl 1):216-22.	
JR	C114	Lane, P., et al., "Cell signaling by nitric oxide," Semin Nephrol. 1999, 19(3):215-29.	
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JR	C117	Levere, et al., "Effect of heme arginate administration on blood pressure in spontaneously hypertensive rats," Clin Invest. 1990, 86(1):213-9.	
JR	C118	Linden, et al., "Fate of haem after parenteral administration of haem arginate to rabbits," J. Pharm. Pharmacol. 1987, 39(2):96-102.	
JR	C119	Lip, et al., "The acute porphyrias," Br. J. Clin. Pract. 1993, 47(1):38-43.	
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JR	C121	Marcelin et al., "Modulating Role of Nitric Oxide Pathway on the Synthesis of PGI ₂ in Rat Endothelial Cells in Culture," Hypertension 1999, 33(4):1297.	
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JR	C123	Marshall et al., "Endothelium-derived relaxing factors. A perspective from in vivo data" Hypertension 1990, 16(4):371-86.	
JR	C124	Martasek et al., "Properties of human kidney heme oxygenase: inhibition by synthetic heme analogues and metalloporphyrins" Biochem Biophys Res Commun. 1988, 157(2):480-87.	
JR	C125	Martasek et al., "Heme arginate lowers blood pressure in spontaneous hypertensive rats (SHR)" Clinical Research 1989, 37:553A.	

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First Named Inventor	John P. Cooke
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Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 10 of 15

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JSC	C126	Martasek et al., "Hemin and L-arginine regulation of blood pressure in spontaneous hypertensive rats" J. Am. Soc. Nephrol. 1991, 2(6):1078-84.	
JN	C127	Martin et al., "Phosphodiesterase inhibitors induce endothelium-dependent relaxation of rat and rabbit aorta by potentiating the effects of spontaneously released endothelium-derived relaxing factor" J. Pharmacol. Exp. Ther. 1986, 237(2):539-47.	
JN	C128	Maxwell et al., "Cardiovascular effects of L-arginine" Curr. Opin. Nephrol. Hypertens. 1998, 7:63-70 (review).	
JN	C129	Maxwell et al., "Limb blood flow during exercise is dependent on nitric oxide" Circulation 1998, 98(4):369-74.	
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JN	C132	Maxwell et al., "L-arginine enhances aerobic exercise capacity in association with augmented nitric oxide production" J. Appl. Physiol. 2001, 90(3):933-38.	
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JN	C134	Milner JA, "Metabolic aberrations associated with arginine deficiency" J. Nutr. 1985, 115(4):516-23.	
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JN	C137	Moncada et al., "The L-arginine nitric-oxide pathway" The New England Journal of Medicine, 1993, 329(27):2002-12.	
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JN	C139	Moncada S, et al., "The biological significance of nitric oxide formation from L-arginine" Biochem. Soc. Trans. 1989, vol. 17(4):642-44.	

Examiner
Signature

Jeffrey E. Russel

Date
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		Attorney Docket Number	080618-0237

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JR	C140	Moncada et al., "International Union of Pharmacology Nomenclature in Nitric Oxide Research" Pharmacol. Rev. 1997, 49(2):137-42.	
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JR	C149	Palmer et al., "Nitric oxide release accounts for the biological activity of endothelium-derived relaxing factor" Nature 1987, 327:524-26.	
JR	C150	Palmer et al., "The biological significance of nitric oxide formation from L-arginine" Biochem. Soc. Trans. 1989, 17(4):642-44.	
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jn	C154	Pearson and Shaw, "Life Extension: A Practical Scientific Approach," Warner Books, Inc., New York 1982, pp. 307-21, 460-85.	
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jn	C160	Radomski MW et al., "Modulation of platelet aggregation by an L-arginine-nitric oxide pathway" Trends Pharmacol. Sci. 1991, (3):87-8.	
jn	C161	Rector et al., "Randomized, double-blind, placebo-controlled study of supplemental oral L-arginine in patients with heart failure" Circulation 1996, 93(12):2135-41.	
jn	C162	Reynolds et al., "Immunomodulatory mechanisms of arginine" Surgery 1988, 104(2):142-51.	
jn	C163	Rubanyi et al., "Superoxide anions and hyperoxia inactivate endothelium-derived relaxing factor" Am. J. Physiol. 1986, 250:H822-H827.	
jn	C164	Rubanyi, "The role of endothelium in cardiovascular homeostasis and diseases" J. of Cardio, Pharm. 1993, 22 (Suppl.) S1-S14.	
jn	C165	Sakuma et al., "Identification of arginine as a precursor of endothelium-derived relaxing factor" Proc. Natl. Acad. Sci. USA 1988, 85(22):8664-67.	
jn	C166	Sakuma et al., "L-Arginine is a Precursor of Endothelium-Derived Relaxing Factor in Various Animal Species and Vascular Beds" in Nitric Oxide from L-Arginine: A Bioregulatory System (Moncada and Higgs, eds.) 1990, Chapter 49, pp. 445-49.	
jn	C167	Sanchez et al., "Testing a mechanism of control in human cholesterol metabolism: relation of arginine and glycine to insulin and glucagon" Atherosclerosis 1988, 71:87-92.	

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JR	C168	Sanchez et al., "Plasma amino acids and the insulin/glucagon ratio as an explanation for the dietary protein modulation of atherosclerosis" Medical Hypotheses 1991, 35:324-29.	
JR	C169	Schaffer et al., "Nitric oxide regulates wound healing" J. Surg. Res. 1996, 63(1):237-40.	
JR	C170	Schwarzacher et al., "Local intramural delivery of L-arginine enhances nitric oxide generation and inhibits lesion formation after balloon angioplasty" Circulation 1997, 95(7):1863-69.	
JR	C171	Seifter et al., "Arginine: an essential amino acid for injured rats" Surgery 1978, (2):224-30.	
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JR	C174	Smith et al., "Role of nitric oxide synthesis in the regulation of coronary vascular tone in the isolated perfused rabbit heart" Cardiovasc. Res. 1992, (5):508-12.	
JR	C175	Snyder et al., "Biological roles of nitric oxide" Sci. Am. 1992, 266(5):68-71, 74-77.	
JR	C176	Solangi et al., "L-arginine protects cyclosporin A-induced blood pressure elevation in spontaneous hypertensive rats" Clinical Research 1990, 38(2):349A.	
JR	C177	Steinsland OS et al., "Biphasic vasoconstriction of the rabbit ear artery" Circ. Res. 1973, (1):49-58.	
JR	C178	Suarez et al., "Modulation of the vascular response of isolated perfused rat kidney to phenylephrine by flow. Role of nitric oxide" Hypertension 1995, 25:1392.	
JR	C179	Tenenbaum et al., "L-Arginine: rediscovery in progress" Cardiology 1998, 90(3):153-59.	
JR	C180	Thadani et al., "Diagnosis and management of porphyria" BMJ. 2000, 17;320(7250):1647-51.	
JR	C181	Thomas G, et al., "Vasodilatory properties of mono-L-arginine-containing compounds" Biochem Biophys Res Commun. 1988, 154(1):332-38.	

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Jeffrey E. Russel

Date
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September 7, 2004

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Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**

Date Submitted: May 21, 2004

(use as many sheets as necessary)

Complete if Known

Application Number	10/618,835
Filing Date	07/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 14 of 15

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
JR	C182	Togashi et al., "A central nervous system action of nitric oxide in blood pressure regulation" J. Pharmacol. Exp. Ther. 1992, 262(1):343-47.	
JR	C183	Umans et al., "Nitric oxide in the regulation of blood flow and arterial pressure" Annu. Rev. Physiol. 1995, 57:771-790.	
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JR	C185	Vallance et al., "Effects of endothelium-derived nitric oxide on peripheral arteriolar tone in man" Lancet 1989, 2(8670):997-1000.	
JR	C186	Vane et al., (Mechanisms of disease) "Regulatory functions of the vascular endothelium" New England J. Med. 1990, 323:27-36.	
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JR	C195	Waller et al., "Conditions for synthesis of antioxidative arginine-xylose maillard reaction products" Synthesis of Antioxidative Products 1983, pp. 125-40.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: May 21, 2004 (use as many sheets as necessary)		Application Number	10/618,835
		Filing Date	07/15/2003
		First Named Inventor	John P. Cooke
		Group Art Unit	1654
		Examiner Name	J. Russel
Sheet	15	of	15
		Attorney Docket Number	080618-0237

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
JR	C196	Wang et al., "Dietary arginine prevents atherogenesis in the coronary artery of the hypercholesterolemic rabbit" J Am College Cardiol. 1994, 23(2):452-58.	
JR	C197	Wascher, "Oral L-arginine supplementation in chronic heart failure" Circulation 1997, 95(6):1674-75.	
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JR	C202	Wu et al., "Arginine metabolism: nitric oxide and beyond" Biochem. J. 1998 336:1-17.	
JR	C203	Wu et al., "Arginine nutrition and cardiovascular function" Am. Society Nutr. Sci. 2000, 130:2626-29. J. Nutr.	
JR	C204	Zeiber et al., "Modulation of coronary vasomotor tone in humans. Progressive endothelial dysfunction with different early stages of coronary atherosclerosis" Circulation 1991 83(2):391-401.	
JR	C205	Zeiber et al., "Endothelial Dysfunction of the Coronary Microvasculature Is Associated With Impaired Coronary Blood Flow Regulation in Patients With Early Atherosclerosis" Circulation 1991, 84(5):1984-92.	
JR	C206	Dialog Search Result for Normosang Synonyms. Chemsearch Database (not dated)	
JR	C207	European Porphyria Initiative, http://www.porphyria-europe.com , selected pages (2-13-2004)	
JR	C208	Stedman's Medical Dictionary, The Williams and Wilkins Co. (23 rd Edition 1976), p. 1124.	

Examiner Signature	Jeffrey E. Russel	Date Considered	September 7, 2004
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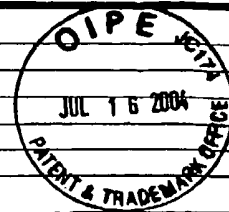
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	10/618,835
Filing Date	7/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237



Sheet	1	of	3
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: July 16, 2004 (use as many sheets as necessary)		Application Number	10/618,835
		Filing Date	7/15/2003
		First Named Inventor	John P. Cooke
		Group Art Unit	1654
		Examiner Name	J. Russel
Sheet	2	of	3
		Attorney Docket Number	080618-0237

FOREIGN PATENT DOCUMENTS

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JR	G23	LEFER ET AL., "Role of Endothelium-derived Relaxing Factor as a Cardioprotective Agent in Myocardial Ischemia", <i>Basil, Karger</i> (1990), pp. 190-197.	
JR	G24	IGNARRO ET AL., "Basic Polyamino Acids Rich in Arginine" <i>Circ. Res.</i> (Feb. 1989), Vol. 64, No. 2, pp. 315-329.	
JR	G25	ROCK ET AL., "L-arginyl-L-lysine and L-arginyl-L-arginine" <i>Med. Sci. Res.</i> (1990), Vol. 18, pp. 165-166.	
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JR	G31	VERMA, et al., <i>Nature</i> , Vol. 389, pp. 239-242 (1997).	
JR	G32	SHEARS, et al., <i>J. Am. Coll. Surg.</i> , Vol. 187, pp. 295-306 (1998).	
JR	G33	SAWA, et al., <i>Circulation</i> , Vol. 96 (Suppl. II) 280-285 (1997).	

Examiner Signature	Jeffrey E. Russel	Date Considered	September 7, 2004
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: July 16, 2004

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Application Number	10/618,835
Filing Date	7/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 3 of 3

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JR	G34	BAI, et al. <i>Ann. Thorac. Surg.</i> , Vol. 66, pp. 814-820 (1998).	
JR	G35	LUI, et al., <i>Current Pharmaceutical Design</i> , Vol. 2, pp. 553-584 (1996).	
JR	G36	MARSHALL, et al., <i>Science</i> , Vol. 269, pp. 1050-1055 (Aug. 1995).	
JR	G37	ORKIN, et al. "Report and Recommendations of the Panel to Assess the NIH Investment on Research in Gene Therapy", (1995).	
JR	G38	ROČIĆ ET AL., "L-arginyl-L-lysine and L-arginyl-L-arginine", <i>Med. Sci. Res.</i> (1990), Vol. 18, pp. 165-166.	
JR	G39	ADAMS ET AL., "Oral L-Arginine Inhibits Platelet Aggregation but Does Not Enhance Endothelium-Dependent Dilation in Healthy Young Men", <i>JACC</i> (October 1995), Vol. 26, No. 4, pp. 1054-1061.	
JR	G40	MAYER ET AL., "Homocysteine and Coronary Atherosclerosis," <i>JACC</i> (March 1, 1996), Vol. 27, No. 3, pp. 517-527.	
JR	G41	Supplementary European Search Report dated May 12, 2004 for EP Application No. 97938163.9	
JR	G42	International Search Report dated August 29, 1994 for PCT Application No. PCT/US94/06203.	
JR	G43	International Search Report dated January 21, 1997 for PCT Application No. PCT/US96/17241.	
JR	G44	International Search Report dated October 10, 1997 for PCT Application No. PCT/US97/13905.	

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